UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

April 8, 2015

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 1677-ELR;
Peroxide Disinfectant and Glass Cleaner RTU
DP Barcode: 424445

From: Lorilyn M. Montford L. Montford 4/23/15
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader MP
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To: Jacqueline Hardy, PM 34/Terria Northern
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Ecolab, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Formulation from the Label:

Active Ingredient(s)	% by wt.
Decanoic Acid	0.39%
Other Ingredients	99.61%
Total	100.00 %

I BACKGROUND

The product, Peroxide Disinfectant and Glass Cleaner RTU (EPA Reg. No. 1677-ELR), is a new product. The applicant requested to register the product as a RTU spray (one-step) disinfectant (bactericide, virucide, fungicide) and non-food contact sanitizer for use on hard, non-porous surfaces in households, hospitals, industrial, institutional, veterinary, animal housing facilities, and commercial environments. The applicant is requesting to utilize the studies from one of their previously registered dilutable products (EPA Reg. No. 1677-238), to support this application. This submission is identical to the 6 oz. per gallon found in their product: 1677-238. The studies used for this submission were conducted at both ATS Labs located at 1285 Corporate Center Drive, Suite 100, Eagan, MN 55121 and also at Ecolab.

The submitted data package contained a letter from the registrant (dated November 11, 2014), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), Statement of No Data Confidentiality Claims, and the proposed label.

II USE DIRECTIONS

The product is designed to clean and disinfect non-food contact counter tops, sinks, exterior surfaces of refrigerators, coolers, stovetops, freezers, shelves, telephones, chairs, desks, shower stalls, tubs, tiles, shower doors, restroom fixtures, toilets, urinals, windows, and mirrors. The product is intended for use on vinyl, painted surfaces, plastic surfaces, glazed tile, linoleum®, plastic such as polyethylene, polypropylene, and polyvinylchloride.

Directions on the proposed label provided the following instructions for the preparation and use of the product as a disinfectant:

Pre-Clean heavily soiled areas. Apply by coarse trigger sprayer to hard, non-porous surfaces. Spray 6-8 inches from the surface; making sure to wet surfaces thoroughly. All surfaces must remain wet for the required time indicated in the directions for use. Wipe surfaces dry with a sponge, mop, or cloth (or allow to air dry). Rinsing is not necessary on non-food contact surfaces. Do not use this product to clean or disinfect glassware, dishes, or silverware.

III AGENCY STANDARD FOR PROPOSED CLAIM

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product batches (at lowest certified limit – LCL), against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC15442). To support products labeled as "hospital disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level for the AOAC Germicidal Spray Method. To support products labeled as "hospital

disinfectants" conducted utilizing the "Use-Dilution Method", killing on 57/60 carriers for *Staphylococcus aureus* and 54/60 carriers for *Pseudomonas aeruginosa* is required to provide effectiveness at the 95% confidence level.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of a disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Fungicides

Disinfectants for Use as Fungicides Against Pathogenic Fungi:

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method has been modified to conform with the appropriate elements to create the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different batches of product must be tested. Killing of the specific pathogenic fungi on all carriers is required.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

This submission is identical to EPA Registration No. 1677-238, at the 6 oz./gallon. Studies submitted to the Agency in support of 1677-238 utilized 35 studies in all (MRID No.'s 48947404 thru 48947438). Claims supported by the original product (1677-238) are used to support this proposed ready to use product (1677-ELR).

V CONCLUSION

Claims supported by the original product (1677-238) are used to support this proposed ready to use product (1677-ELR). The following bactericidal claims are **supported** with a contact time of 5 minutes in the presence of a 5% organic soil load, 400 ppm AOAC Hard Water and conducted under the AOAC Germicidal Spray Method:

-*Pseudomonas aeruginosa* (ATCC 15442)
-*Staphylococcus aureus* (ATCC 6538)
-*Salmonella enterica* (ATCC10708)
-*Klebsiella pneumoniae* (ATCC 4352)
-*Shigella flexneri* (ATCC 9380)
-*Streptococcus pyogenes* (19615)
-*Shigella dysenteriae* (ATCC 29026)
-*Listeria monocytogenes* (ATCC 7644)
-*Staphylococcus aureus* (ATCC (VISA) (ATCC 700788)
-*Staphylococcus aureus* (MRSA) (ATCC 33592)
-*Klebsiella pneumoniae* (Carbapenemase producer) (KPC) (ATCC BAA-1705)
-*Enterococcus faecalis* (VRE) (ATCC 51299)
-*Bordetella pertussis* (ATCC 12743)

-*Proteus mirabilis* (ATCC 7002) – **3 minute contact time**

The following virucidal claims are supported and are to be included with this submission with a contact time of 5 minutes in the presence of a 5% organic soil load and 400 ppm AOAC Hard Water for hard, non-porous surfaces:

-Vaccinia Virus (ATCC VR-119)
-Respiratory Syncytial Virus (ATCC VR-26)
-Hepatitis B Virus
-Human Coronavirus (SARS) (ATCC VR-740)
-Canine Parvovirus (ATCC VR-2017)

-Canine Distemper Virus (ATCC VR-128)
-Newcastle Disease Virus (ATCC VR-108)
-Poliovirus (chat strain)
-Murine Norovirus (Strain MNV-1.CW1)
-Rotavirus (Stain WA)
-Norovirus (Feline Calicivirus ATCC VR-782)
-Herpes Simplex Virus Type 1 (ATCC VR-733)
-Rhinovirus Type 37 (ATCC VR-1147)
-Influenza A Virus H1N1
-Adenovirus type 5 (ATCC VR-5)
-Herpes Simplex Virus Type 2 (ATCC VR-734)

-Human Immunodeficiency Virus Type 1 (HIV-type 1) – **1 minute contact time**.

The following fungicidal claims are supported and are to be included with this submission with a contact time of 5 minutes in the presence of a 5% organic soil load and 400 ppm AOAC Hard Water on hard, non-porous surfaces (AOAC Germicidal Spray Method):

-*Candida albicans* (ATCC 10231)

The following **non-food contact sanitization** claims are to be included with this submission with a contact time of 90 seconds in the presence of a 5% organic soil load and 400 ppm AOAC Hard Water on hard, non-porous surfaces (AOAC Germicidal Spray Method):

-*Staphylococcus aureus* (ATCC 6538)
-*Enterobacter aerogenes* (ATCC 13048)
-*Salmonella enterica* (ATCC 10708)
-*Escherichia coli* (ATCC 11229)
-*Pseudomonas aeruginosa* (ATCC 15442)
-*Enterococcus faecalis* (ATCC29212)

-*Listeria monocytogenes* (ATCC 7644) - **200 ppm AOAC hard water** included

The following bactericidal claims are **supported** and are to be included with this submission with a contact time of 5 minutes in the presence of a 5% organic soil load and 200 ppm AOAC Hard Water on hard, non-porous surfaces (AOAC Germicidal Spray Method):

-*Escherichia coli* (O157:H7) (ATCC 43895)
-*Enterobacter aerogenes* (ATCC 13048)

The following bactericidal and virucidal claims are to be included with this submission with a contact time of 3 minutes in the presence of a 5% organic soil load, and 200 ppm AOAC Hard Water on hard, non-porous surfaces (AOAC Germicidal Spray Method):

-*Pseudomonas aeruginosa* (ATCC 15442)
-*Staphylococcus aureus* (ATCC 6538)
-*Salmonella enterica* (ATCC 10708)

-*Klebsiella pneumoniae* (ATCC 4352)
-*Staphylococcus aureus* (CA-MRSA) (BAA-1683)
-*Staphylococcus aureus* (MRSA) (ATCC 33592)
-*Serratia marcescens* (ATCC 14756)
-*Bordetella bronchiseptica* (ATCC 31437)

-Norovirus (Feline Calicivirus) (ATCC VR-782)
-Rhinovirus Type 37 (ATCC VR-1147)
-Influenza A Virus H1N1

VI RECOMMENDATIONS

1. The proposed label claims that the product, Peroxide Disinfectant and Glass Cleaner RTU, is an effective ready to use disinfectant (with bactericidal, virucidal and fungicidal activity) against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load (400 ppm and 200 ppm AOAC Hard Water as specified above) for the specified contact times listed above.

Data submitted support these claims.

The following changes are recommended for the proposed label:

1. Please correct the spelling of the organism, "*Klebsiella pneumonia*" throughout the proposed label to read, "*Klebsiella pneumonia**e***"

2. On page 10 of the proposed label, please indicate "for external use only" next to the term, "Difibrillator". There are difibrillator's that are implanted into the body as well as external defibrillator apparatus'.

3. On pages 4 and 5, please remove the statements, "Viral Qualification Test" under each Virucidal section. Please replace those statements with the appropriate AOAC or ASTM Method name used to test against the viruses supported in the label.